

WHAT IS CLAIMED:

1. A balloon catheter, comprising
 - a) an elongated shaft having at least one lumen therein; and
 - b) a balloon on a distal shaft section having a proximal and a
5 distal skirt section secured to the elongated shaft so that an inflatable interior of the
balloon is in fluid communication with the shaft lumen, and having at least one
visible mark visible from an outer surface of the balloon, the visible mark being
selected from the group consisting of an ink coating mark, a titanium oxide mark,
and a scorch mark.
- 10 2. The balloon catheter of claim 1 wherein the visible mark is
nonradiopaque.
3. The balloon catheter of claim 1 wherein the visible mark is aligned
with a visualization system marker on a portion of the shaft extending through the
inflatable interior of the balloon.
- 15 4. The balloon catheter of claim 1 wherein the balloon has an inflated
configuration with an inflated working length, a proximal tapered section between
the inflated working length and the proximal skirt section of the balloon, and a
distal tapered section between the inflated working length and the distal skirt
section of the balloon, and the balloon has a proximal visible mark at a proximal
20 end of the working length, and a distal visible mark at a distal end of the working
length.

5. The balloon catheter of claim 4 wherein the catheter shaft comprises an inner tubular member extending through the inflatable interior of the balloon, the inner tubular member having two or more visualization system markers, and the proximal and distal visible marks are radially aligned with the visualization system markers of the inner tubular member.

6. The balloon catheter of claim 4 wherein the balloon catheter is a stent delivery catheter with a stent mounted on a working length of the balloon for delivery and deployment within a patient's body lumen, and the proximal visible mark is located at or proximally adjacent to a proximal end of the stent and the distal visible mark is located at or distally adjacent to a distal end of the stent.

7. The balloon catheter of claim 4 wherein the proximal and distal marks extend at least partially around the circumference of the balloon.

8. The balloon catheter of claim 4 wherein the proximal and distal marks extend completely around the circumference of the balloon.

9. The balloon catheter of claim 4 wherein the visible marks are not located at a central section of the balloon located between the proximal and distal visible marks.

10. The balloon catheter of claim 1 wherein the balloon has a deflated configuration with one or more wings wrapped around the balloon before inflation of the balloon in a patient's body lumen, and the visible mark extends along an edge of the wing.

11. The balloon catheter of claim 1 wherein the visible mark is a dashed, dotted, or continuous line.

12. A balloon catheter, comprising:

5 a) an elongated shaft having a proximal end, a distal end, and an inflation lumen; and

b) a balloon on a distal shaft section, having an interior in fluid communication with the inflation lumen of the shaft, and having a proximal and a distal skirt section bonded to the shaft, an inflated configuration and a deflated configuration, an inflated working length and a proximal inflated tapered section and a distal inflated tapered section in the inflated configuration, and a proximal visible mark at a proximal end of the working length and a distal visible mark at a distal end of the working length, the proximal and distal visible marks extending at least partially around the balloon circumference and being a nonradiopaque material.

15 13. The balloon catheter of claim 12 wherein the proximal and distal visible marks are selected from the group consisting of an ink coating mark, a titanium oxide mark, and a scorch mark.

20 14. A method of making a balloon catheter having an elongated shaft and a balloon on a distal shaft section, comprising making at least one visible mark visible from an outer surface of the balloon using a method selected from the group consisting of scorching the balloon material to form a scorch mark, coating the balloon material with an ink to form an ink coating mark, and converting titanium dioxide loaded in a wall of the balloon to titanium oxide to form a titanium oxide mark.

15. The method of claim 14 wherein the balloon has an inflated configuration with an inflated working length, a proximal inflated tapered section between the inflated working length and a proximal skirt section of the balloon, and distal inflated tapered section between the inflated working length and a distal skirt section of the balloon, and making the visible mark comprises forming a proximal visible mark at a proximal end of the working length and a distal visible mark at a distal end of the working length.

16. The method of claim 15 wherein the elongated shaft comprises an inner tubular member defining a guidewire lumen and an outer tubular member defining an inflation lumen, and including, after the proximal and distal visible marks are made, providing the shaft inner tubular member extending through an interior of the balloon and radially aligning visualization system markers on the inner tubular member with the proximal and distal visible marks on the balloon to align the inner tubular member, and securing the distal skirt section of the balloon to the aligned inner tubular member.

17. The method of claim 15 wherein the proximal and distal visible marks are made before or after the balloon proximal and distal skirt section are secured to the shaft, and including, after the marks are formed, mounting a stent on the balloon working length with the stent between the proximal and distal visible marks.

18. The method of claim 15 including inflating the balloon to the inflated configuration before the proximal and distal visible marks are made, and wherein the proximal and distal visible marks are formed on the balloon in the inflated configuration.

19. The method of claim 15 wherein the proximal and distal visible marks comprise scorch marks, and the scorch marks are formed on the balloon in a deflated configuration.

20. The method of claim 14 wherein the balloon has an inflated configuration with an inflated working length, a proximal inflated tapered section between the inflated working length and a proximal skirt section of the balloon, and distal inflated tapered section between the inflated working length and a distal skirt section of the balloon, and wherein the visible mark is formed along an edge of a wing of the balloon in a deflated folded configuration after the balloon proximal and distal skirts sections are secured to the elongated shaft.

21. The method of claim 20 including pressing and twisting the deflated folded balloon after the visible mark is formed.

22. The method of claim 20 including mounting a stent on the working length of the balloon after the visible mark is formed.

23. The method of claim 14 wherein the visible mark is nonradiopaque and the mark is formed as a dashed, dotted, or continuous line.

24. The method of claim 14 wherein the visible mark is ink applied to the balloon by a method selected from the group consisting of wiping, spraying, masked dipping, and electrostatic attraction.

25. The method of claim 14 wherein the visible mark is scorched balloon material formed by exposing the balloon to laser radiation.

26. The method of claim 14 wherein the titanium dioxide loaded in the wall of the balloon is converted to titanium oxide by exposing a portion of the
5 balloon to ultraviolet radiation to form the titanium oxide mark.

27. A stent delivery balloon catheter, comprising:

a) an elongated shaft having a proximal end, a distal end, and an inflation lumen; and

b) a balloon on a distal shaft section, having an interior in fluid
10 communication with the inflation lumen of the shaft, and having a proximal and a distal skirt section bonded to the shaft, an inflated configuration and a deflated configuration, a working length with an expandable stent mounted on the working length, a proximal visible mark proximal to a proximal end of the stent, and a distal visible mark distal to a distal end of the stent, the proximal and distal visible marks
15 extending at least partially around the balloon circumference and being a nonradiopaque material.

28. The stent delivery balloon catheter of claim 27 wherein the visible marks are selected from the group consisting of an ink coating mark, a titanium oxide mark, and a scorch mark.